T.H. 8-5-03 #13/Subst spec

MODULAR REVISION PROSTHESIS

BACKGROUND OF THE INVENTION

[0001] In order to restore the function of a loose artificial hip joint, various major and minor problems have to be surmounted. The major problems are the anchorage problems related to achieving stable fixation despite often large defects remaining in the bony support after the joint components have been removed. Minor problems involve filling in the defects with bone from tissue banks; this is accomplished using "morcellized bone" plastics of the appropriate size. (Lamerigts, N. M. P., 1998. Proefschrift an der katholischen Universitt Niymegen.) Once the bony support structure has been reinforced with bone from tissue banks, the corresponding joint replacement components can be cemented in.

[0002] In order to use such a procedure, the bony structures must be sufficiently stable to achieve a stable overall anchorage. However, these bone structures often are no longer present, and as a result, very special demands are placed on the implant. Therefore, there is a genuine need for systems that can be adapted to the given situation that is when large defects are present, and that take various biomechanical fixation principles into account. With this background as a foundation, a novel approach to the problem of revision operations (i.e., replacement of the femur component of a prosthesis) was

unexpectedly discovered.

Prior Art

[0003] The extent of the defects in the bony femur bed after the removal of a loose, previously implanted prosthesis may vary. This has led to attempts to classify bone defects, for example in the DGOT (Bettin, D., Katthagen, B. D., (1997), Die DGOT-Klassifkation von Knochendefekten bei Huft-Totalendoprothese-Rev- isionsoperationen [The DGOT Classification of Bone Defects in Total Hip Endoprosthesis Revision Operations], Z. Orthop. 135). In some cases, the bone damage is considerable. Treatment of the loose prosthesis or implant components involves complete removal of the components and, if present, the bone cement that was previously used, as well as all of the connective tissue surrounding the previous implant, that connects the implant to the bone. Not until this has been done can one realistically assess the extent of bone loss. Often, the only way to anchor a new implant component is to reach beyond all defects and anchor the component deep in the portion of the femur diaphysis (the shaft of the long bone) that is still healthy, frequently without the use of cement.

[0004] Another method is to reconstruct the bone with morcellized bone from tissue banks and use cement to reattach such a component. This is described in detail in Lamerigts, N.

M., (1998), The Incorporative Process of Morcellized Bone Graft. Proefschrift University Nijmegen (Catholic University). In both cases, proximal anchoring, that is, near the upper end of the bone is usually not stable. The implants in the femur are usually very long and heavy, and much poorer results are obtained than in primary operations.

[0005] Tests and simple experiments on cadaver bones unexpectedly revealed very efficient ways to anchor and fix femur components in defective bone support structures, even components having short shafts.

SUMMARY OF THE INVENTION

A prosthesis anchorage system comprises a modular replacement insert for the femur for repairing artificial hip joints. The anchorage system provides a femur stem that is segmented and will insert into the femur canal, and can be elongated to a length so that portions of the femur stem will be aligned in the canal with bone that provides a solid holding action for the stem when replacing a previously installed stem that has become loosened. The base modular section includes an axial or central cylinder that inserts into adjacent stem sections and which serves to hold the stem sections in alignment. At the proximal end of the femur, a shoulder stem

section is used. The shoulder stem section has a surface that will permit attaching a mating shoulder on a neck and head prosthesis securely with tension carrying members.

The length of the femur stem inserted into the femur canal can be adjusted to accommodate a wide variety of conditions when a hip joint is to be replaced.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a view of femur shaft for a prosthesis illustrated schematically in place;

FIG. 2 is a fragmentary sectional view taken as on line 2--2 in FIG. 3-1; and

FIG. 3 is a view similar to FIG. 1 with a modified construction.

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DESCRIPTION OF THE INVENTION

[0006] The modular tension anchorage system of the present invention allows one to adapt the implant to various defect conditions encountered in revising (replacing) a loose femur implant stem or shaft component. The invention takes various defects that have to be dealt with into account with regard to the stem or shaft length and various additional anchoring possibilities in the proximal femur canal. The modular system

essentially is comprised of a femoral or medullary stem or shaft (100), made up of one or more stem segments. The femoral stem or shaft 100 corresponds to a cylinder opening in the bone located around the medullary canal axis.

[0007] Various stem segments must be used in sequence along this open cylinder along the medullary or femural canal: the base or distal segment (100.3) may be of various lengths, and it is always comprised of the tip (102) and an axial or center cylinder (103). One stem segment--in rare instances two or more stem segments (100.2, 100.3)--may be arranged on top of each other along the axial cylinder (103). A shoulder segment (100.1) always follows or is placed above the inserted stem.. The contact surface (105) on the proximal or upper end the base stem segment 100.3 is concave. The corresponding or mating distal end of the center or next higher stem segment is convex, or vice versa. The corresponding or mating ends of the stem segments may also engage one another conically or in other words with the end of one segment having a cone shape and the end of the adjacent segment having a mating receptacle. A curved, interlocking surface design between the ends of the adjacent segments has proved to be particularly effective. Such a surface prevents rotation and takes tension loads on the lateral side of the stem and compression loads on the medial side of the stem into

account.

[0008] The axial cylinder (103) and the corresponding hole in which the axial cylinder 103 fits in the adjacent stem segments or shoulder segment 100.1 are smooth, or they are structured with a locating groove and nubs to prevent rotation. The length of the prosthesis is determined based on how far it needs to extend into the femur canal so the distal end is beyond bone defects. A center stem segment (100.2) is inserted with the hole (106) receiving the central axial cylinder (103) that is also in the base segment (100.3). The cross section (108) of the metaphysial or proximal shoulder segment (100.1) as shown in Figure 2 consists of the lateral cylinder (112), which is hollow (109) , for receiving the central axial cylinder 103. The connecting segment (111), joins the lateral cylinder (112) and the medial portion (110), and the connecting segment (111) forms the convex-concave (104) convex contour of the dorsal side. The channel for the tension anchor (thrust rod) (50) passes through bore (113) across the extended areas of the medial portion of the metaphysial shoulder segment (100.1).

[0009] The metaphysial shoulder segment (100.1) exhibits a parabolically curved concave outer surface (See Figures 1 and 3) medially, ventrally, and dorsally in a U-shape for force

transfer. The shoulder or base (200) of the cone (300) of the head prosthesis (301) has additional holes for tension anchors (60) and cables ((70) in a bore (71)). The thrust anchor (50) is held in the cone (301) of the prosthesis (300), and axially through the cone (301) like a tension screw , as shown, having a washer (54) and screw head (51) so the anchor (50) can be threaded into a nut (55) in the cone (301). The nut (55) in the cone (301) is prevented from turning. The other tension anchors can also be embodied as simple tension screws (for example 60), in which case the screw head would be located in the shoulder (200) and the tension screw would extend through the shoulder so the thread would be located on and threaded into the lateral side of the femur bone.

SUBSTITUTE SPECIFICATION

EXAMPLE

[0011] After making absolutely sure the diagnosis is loosening of the implanted hip prosthesis, the joint is exposed via the old access incision. The scar tissue is carefully removed, the joint is dislocated or separated from the femur shaft, and the old, loose femur shaft is removed. Usually the old shaft can simply be pulled out; in a rare case, an instrument needs to be used to hammer it out. The old bone cement and connective tissue in the femur canal are then carefully removed. An ultrasonic

titanium chisel can be very useful in this procedure.

[0012] The bone channel, or femur canal from which the connective tissue has been removed, is rinsed carefully using a jet lavage, and the bony structure is then reconstructed.To do this, tissue bank bone is ground up in a mill, and this "morcellized" bone is mixed in a 50:50 ratio with a shell-shaped bone ceramic used as the granulate--for example: Synthacer.RTM.--and it is then forced up against the walls in the intermedullary or femur canal with the aid of a trial shaft. Drainage tubes are then inserted into the canal via the fossa intertrochanterica, and a vacuum is applied to these drainage tubes.

Then, the intermedullary tissue is carefully rinsed with H_2O_2 and the canal is filled with bone cement using a snorkel application system. The prosthesis stem assembly of the necessary length stem segments including at least the base stem segment (100.3) and, if needed, one other stem segment, and also the shoulder segment (100.1) are axially inserted into the femur bone canal, which is filled with bone cement and morcellized bone. After the cement has cured with the new femur stem and shoulder segment in place, a hole (113) is drilled in the prosthesis shoulder segment along the axis of the cone (300), and, if necessary, additional holes are drilled through

the shoulder segment and cone, and the cone (300) is stably anchored into the bone of the femur by means of tension anchors (50) or tension screws (60) that extend through the femur and shoulder segment to clamp the cone in place. The screws (60) can also be advantageously screwed in through the still-soft cement, provided that holes were drilled in advance in the femur. The advantage of this is that the bone cement shrinks onto the screw thread.

[0013] If conditions in the femur bone are still stable after removal of the old implant, the prosthesis stem system can also be anchored stably in the femur bone without using bone cement.